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LENGTHENING THE STEM: ALLOWING FEDERALLY FUNDED RESEARCHERS TO DERIVE HUMAN PLURIPOTENT STEM CELLS FROM EMBRYOS

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Recent developments in fetal tissue research and stem cell research have led to dramatic breakthroughs in the search for cures for Parkinson's disease, Alzheimer's disease, diabetes, and a host of neurological disorders. Because this research involves fetal tissue and stem cells from human embryos, many complicated ethical and legal implications surround it. This Note explores the history of fetal tissue research and stem cell research, examines the surrounding ethical and legal issues, looks at the current state of federal law, and concludes that Congress should allow federally funded researchers to derive stem cells from discarded human embryos obtained from in vitro fertilization clinics.

Fetal tissue research and stem cell research both hold enormous promise for victims of Parkinson's disease, Alzheimer's disease, other neurological disorders, and diabetes. New treatments and, ultimately, cures may be on the horizon. Stem cell research in particular has the potential to affect virtually every realm of medicine in a dramatic way. It is critical that this research be supported and broadened.

This Note argues that Congress should grant federal funding for the derivation of stem cells from human embryos. The law currently allows research on stem cells derived from discarded human embryos as long as the procedures through which the stem cells are removed from the embryos are not federally funded. Part I of this Note examines the history and development of (ex-utero) fetal tissue research and stem cell research. Part II discusses the ethical and legal issues surrounding this research. Part III examines the current state of federal law on fetal tissue research and stem cell research. Finally, the Note concludes that expanding federal legislation and National Institutes of Health (NIH) guidelines through the passage of the Stem Cell Research Act of 2001 will allow federally funded researchers to derive stem cells

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from discarded embryos obtained from in vitro fertilization (IVF) clinics, potentially accelerating advances in the study of diseases and expediting the development of new treatments.

I. HISTORY AND DEVELOPMENT OF FETAL TISSUE RESEARCH AND STEM CELL RESEARCH

A. Fetal Tissue Research

Extensive use of fetal tissue for medical research in the United States began in the 1950s when Dr. Jonas Salk used human fetal kidney cells to develop the polio vaccine.[1] Researchers soon transplanted fetal thymus glands[2] into children with thymus deficiencies in order to allow recipients' immune rejection systems to operate normally.[3] Scientists believe fetal tissue research could hold countless benefits for millions suffering from a host of neurological diseases,[4] particularly Parkinson's disease.[5]

Fetal tissue is preferred to adult tissue because fetal cells maintain their plasticity,[6] change shape to place themselves in the correct location, are able to integrate and grow in new surroundings, and are less immunogenic than adult cells, making rejection

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1. Daniel E. Koshland, Jr., Editorial, *Fetal Tissue Research*, 256 SCI. 1741, 1741 (1992) (describing the benefits of fetal tissue research).

2. During fetal development, the thymus gland processes many of the body's lymphocytes, which travel through the bloodstream seeding lymph nodes and lymphatic tissue. Encyclopedia.com, *Thymus Gland*, *at* http://www.encyclopedia.com/printable/12858.html (last visited Feb. 13, 2001) (on file with the *University of Michigan Journal of Law Reform*). A heterogeneous group of cells, known as T-cells, undergoes this process, which is essential in establishing the body's immune system. *Id.*

3. RUSSELL SCOTT, THE BODY AS PROPERTY 37 (1981) (describing uses of fetal tissue research).

4. Gina Kolata, *Federal Agency Bars Implanting of Fetal Tissue*, N.Y. TIMES, Apr. 16, 1988, at F1 (discussing the potential use of fetal tissue for treating certain incurable diseases).

5. Parkinson's disease is a slowly progressive degenerative disease affecting a small area of cells in the middle part of the brain. Nat'l Parkinson Foundation, *What the Patient Should Know*, *at* http://www.parkinson.org/pdedu.htm (last visited Feb. 26, 2001) (on file with the *University of Michigan Journal of Law Reform*) (providing an overview of Parkinson's disease). The degeneration of these cells can produce one or more of the typical signs of Parkinson's disease, including tremors, slow movement, stiff limbs, balance problems, and depression. *Id.* Parkinson's disease affects approximately 1.5 million Americans, fifteen percent of whom are diagnosed before age fifty; one of every 100 people over sixty years old is affected by the disease. *Id.*

6. Plasticity is the ability of tissue to undergo differentiation, which allows it to renew destroyed or injured tissue. *See Medical Applications of Fetal Transplantation Tissue*, 263 JAMA 565 *passim* (1990).

less likely.[7] Additionally, the supply of fetal tissue is far more abundant than the supply of tissue voluntarily donated by adults.[8]

In the wake of the United States Supreme Court's decision in *Roe v. Wade*[9], federal regulations mandated that fetal tissue used in research be obtained from either miscarried fetuses or fetuses aborted due to ectopic pregnancies in which the fetus implants in the fallopian tube instead of the uterus and cannot be carried to term.[10] Scientists, however, prefer first-trimester fetuses aborted through elective procedures because tissue obtained through miscarriages and ectopic pregnancies usually has pathological flaws.[11] Tissue from an otherwise healthy, electively aborted fetus is useful for a multitude of research and transplantation purposes, whereas the usefulness of tissue obtained from miscarriages and ectopic pregnancies is limited. Because it originates from a fetus that was, for some pathological reason, rejected by a pregnant woman's body, such tissue will not prove helpful in the search for treatments and cures for diseases and conditions unrelated to pregnancy.

In a study conducted at the University of Colorado at Denver, forty patients with advanced Parkinson's disease received surgical implants of fetal dopaminergic cells[12] or underwent a sham surgical procedure.[13] Positron emission tomography (PET)[14] demonstrated

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7. *See id.*

8. In 1997, the most recent year for which data is available, there were 1,186,039 legally induced abortions in the United States reported to the Centers for Disease Control and Prevention. Centers for Disease Control and Prevention, *Abortion Surveillance—United States, 1997, at* http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4911a1.html (last visited Dec. 1, 2000) (on file with the *University of Michigan Journal of Law Reform*) (listing abortion statistics). According to the United Network for Organ Sharing, which compiles national tissue and organ transplant data, there were 10,576 cadaveric and living donors in 1999. United Network for Organ Sharing, *Critical Data, Facts About Transplantation, at* http://www.unos.org/Newsroom/critdata_main.htm (last visited Apr. 5, 2001) (on file with the *University of Michigan Journal of Law Reform*). More than 75,000 patients are currently waiting for transplants. *Id.*

9. 410 U.S. 113 (1973).

10. See discussion *infra* Part III.A.

11. Kathy A. Fackelmann, *Study Sizes Up Fetal Cells for Transplant*, 147 SCI. NEWS 6, 6 (1995).

12. Dopamine is a chemical in the brain that plays a crucial role in movement and cognition. The degeneration of dopamine produces the symptoms of Parkinson's disease. Fetal dopaminergic cells replace the lost dopamine in Parkinson's patients. PHILIP G. STRANGE, BRAIN BIOCHEMISTRY AND BRAIN DISORDERS 163–71 (1992).

13. Larry Husten, *Fetal-Cell-Implantation Trial Yields Mixed Results*, 353 LANCET 1501, 1501 (1999) (discussing the first reported randomized, placebo-controlled trial of implantation of fetal cells to stimulate dopamine activity in patients with Parkinson's disease).

14. This technology monitors biochemical changes within the body by detecting and modeling concentrations of radioactivity in particular regions of the body. *See* Dep't of Biological & Agricultural Eng'g, North Carolina State Univ., *Functions of PET, at*

that dopamine activity increased more than twenty percent in more than half of the patients in the group receiving implants, compared with zero percent of the placebo group patients.[15] More than half of the patients under sixty years old who received implants experienced significant improvements in movement.[16] These patients were younger with greater brain plasticity (their brains were able to repair injured tissue more easily), which may account for the more marked improvement in their movement.[17]

Another degenerative brain disorder, Huntington's disease, has attracted the attention of researchers in France.[18] Clinical trials are underway to treat the disease using fetal tissue.[19] Five patients with Huntington's disease had fetal cells that had already begun differentiating into nerve tissue implanted into the parts of their brains controlling movement.[20] Three of the five patients demonstrated improved movement and cognitive function.[21] The promising results of clinical trials such as these likely will lead to more studies of this kind.

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http://www.bae.ncsu.edu/bae/courses/bae590f/1995/mullen/functions.html (last visited Mar. 15, 2001) (on file with the *University of Michigan Journal of Law Reform*).

15. Husten, *supra* note 13, at 1501.

16. *Id.*

17. *Id.* It was recently reported that symptoms intensified due to fetal cell growth in about fifteen percent of the patients receiving fetal cell implants. Curt R. Freed et al., *Transplantation of Embryonic Dopamine Neurons for Severe Parkinson's Disease*, 344 NEW ENG. J. MED. 710, 716, 718 (2001); Gina Kolata, *Parkinson's Research Is Set Back by Failure of Fetal Cell Implants*, N.Y. TIMES, Mar. 8, 2001, at A1. Hours after the findings of the study were released, Nightlight Christian Adoptions, a pro-life organization, filed a lawsuit demanding that the NIH stop funding research with stem cells derived from human embryos. Dawn MacKeen, *Controversial Cell Research Takes a Hit*, SALON.COM, Mar. 9, 2001, *at* http://www.salon.com/mwt/feature/2001/03/09/stem_cells/index.html (on file with the *University of Michigan Journal of Law Reform*). Although opponents of fetal tissue research and stem cell research may be buoyed by the results of the Parkinson's study, these results only point to the need for further research and studies. *See* Editorial, *A Setback in Parkinson's Research*, N.Y. TIMES, Mar. 9, 2001, at A20.

18. Huntington's disease, which affects more than 250,000 Americans, is a hereditary, degenerative brain disorder for which there is no known effective treatment or cure. Huntington's Disease Soc'y of Am., *What is Huntington's Disease?*, *at* http://www.hdsa.org/about/about.pl?whatishd (last visited Mar. 15, 2001) (on file with the *University of Michigan Journal of Law Reform*). Each child of a person with the disease, which crosses all racial, ethnic, and gender barriers, has a fifty percent chance of inheriting it. *Id.* Anyone who carries the gene will develop the disease, and many people at risk choose to avoid taking a test to determine if they are carriers. *Id.* Early symptoms of the disease, which usually strikes victims between the ages of thirty and forty-five, include forgetfulness, involuntary twitching, and lack of coordination. *Id.* As the disease progresses, victims lose the ability to walk, speak, and swallow, eventually deteriorating to the point where they are unable to care for themselves. *Id.* Death often results from choking, infection, or heart failure. *Id.*

19. Jonathan Knight et al., *Reach for the Prize*, NEW SCIENTIST, Nov. 18, 2000, at 10, 11 (discussing highlights from the annual conference of the Society for Neuroscience).

20. *Id.*

21. *Id.*

B. Stem Cell Research

Stem cell research holds even more promise than fetal tissue research for treating virtually all diseases.[22] Even though they cannot become an entire human being, human pluripotent stem cells (HPSCs) have the ability to divide from human embryos and give rise to most of the specialized cells and tissues of the body.[23] HPSCs are derived from embryos created for the purposes of fertility treatment and in excess of clinical need.[24] HPSCs are removed from the embryo after the sperm has fertilized the egg at the blastocyst stage,[25] the point at which embryos are frozen in storage.[26]

HPSCs have unique abilities to renew themselves and form many different cell types, even complex tissues.[27] On the other hand, scientific evidence suggests that the full potential of adult stem cells is more limited.[28] Adult stem cells may be able to divide

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22. In 1998, David Thomson, a researcher at the University of Wisconsin at Madison, isolated human pluripotent stem cells (HPSCs) from human embryos that were a few days old. After four to five months of undifferentiated proliferation, these cells maintained the potential to form derivatives of embryonic germ layers, cartilage, bone, muscle, and neural parts. James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCI. 1145, 1145–46 (1998).

23. *NIH Fact Sheet on Human Pluripotent Stem Cell Research Guidelines, at* http://www.nih.gov/news/stemcell/stemfactsheet.htm (last visited Mar. 15, 2001) (on file with the *University of Michigan Journal of Law Reform*) (discussing HPSCs and contrasting them with human totipotent stem cells, which do have the potential to become entire human beings).

24. Nat'l Insts. of Health, *National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, at* http://www.nih.gov/news/stemcell/stemcellguidelines.htm (last visited Mar. 15, 2001) [hereinafter *Guidelines on Pluripotent Stem Cells*] (on file with the *University of Michigan Journal of Law Reform*).

25. Gabriel S. Gross, Comment, *Federally Funding Human Embryonic Stem Cell Research: An Administrative Analysis*, 2000 WIS. L. REV. 855, 856–57.

26. John A. Robertson, *In the Beginning: The Legal Status of Early Embryos*, 76 VA. L. REV. 437, 440 (1990).

27. The stem cells of a particular tissue are defined as "(a) undifferentiated cells (i.e. lacking certain tissue specific differentiation markers), (b) capable of proliferation, (c) able to self-maintain the population, (d) able to produce a large number of differentiated, functional progeny, (e) able to regenerate the tissue after injury, and (f) flexible use of these options." Markus Loeffler & Christopher S. Potten, *Stem Cells and Cellular Pedigrees—A Conceptual Introduction, in* STEM CELLS 1, 5 (C.S. Potten ed., 1997).

28. Nat'l Insts. of Health, *NIH Statement Before the Senate Appropriations Subcommittee, at* http://www.nih.gov/news/stemcell/State.htm (reprinting the statement of Dr. Allen M. Spiegel, Director of the National Institute of Diabetes and Digestive and Kidney Diseases, and Dr. Gerald D. Fischbach, Director of the National Institute of Neurological Disorders and Stroke) (last visited Oct. 14, 2000) [hereinafter *NIH Statement*] (on file with the *University of Michigan Journal of Law Reform*). In three separate experiments, stem cells from bone marrow repaired damaged heart tissue in animals. Nicholas Wade, *Stem Cells Yield Promising Results*, N.Y. TIMES, Mar. 30, 2001, at A1. In one of these experiments, Dr. Piero Anversa of New York Medical College and Dr. Donald Orlic of the NIH injected primitive stem cells from a donor mouse's bone marrow into mice in which heart attacks had been induced and

only a limited number of times, which reduces their utility in producing adequate numbers of well-characterized cells for therapies.[29] Adult stem cells also may be less robust than HPSCs, making them more susceptible to disease once transplanted into the body.[30]

HPSCs could be used to generate cells and tissues for cell transplantation therapies resulting from the dysfunction of specific cells and tissues and to create a renewable supply of cells, tissues, and organs.[31] Because the demand for cells, tissues, and organs for transplantation far exceeds the supply, HPSCs could save the lives of thousands of people who would otherwise die while waiting for transplants.[32]

Furthermore, HPSCs show great promise in curing type I diabetes, or juvenile diabetes, which is characterized by the body's inability to produce insulin, a hormone necessary for glucose metabolism.[33] HPSCs have the potential to provide a limitless supply of islet cells, the cells needed for transplantation in type I diabetes patients.[34] Due to the shortage of islet cells, only about five percent of those with diabetes who have received islet cell transplants have been able to stay off insulin for more than a year.[35] Utilizing HPSCs to generate a vast source of islet cells could dramatically increase the currently low success rate of islet cell transplants.[36]

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found that the stem cells generated new heart tissue. This was the first time that new heart tissue had been generated from injected cells. Donald Orlic et al., *Bone Marrow Cells Regenerate Infarcted Myocardium*, 410 NATURE 701, 701–05 (2001). Clinical trials in humans are at least a year away, see Wade *supra*, and, although this use of adult stem cells looks promising, it does not obviate the need for continued research using HPSCs. *See* Nicholas Wade, *Findings Deepen Debate on Using Embryonic Cells*, N.Y. TIMES, Apr. 3, 2001, at D1. Another new study shows that human fat may be a potentially rich source of adult stem cells. *See* Michael D. Lemonick, *Who Will Live Longest?*, TIME, Apr. 23, 2001, at 64. Researchers at the University of California at Los Angeles and the University of Pittsburgh obtained stem cells from liposuctioned human fat and made them grow into bone, muscle, and cartilage cells. *Id.* Before human clinical trials occur, however, scientists must make sure that the stem cells do not form tumors or revert to their original form—turning bone to fat. Emily Sohn, *Therapy by the Pound*, U.S. NEWS & WORLD REP., Apr. 23, 2001, at 54.

29. *NIH Statement*, *supra* note 28.

30. *Id.*

31. *Id.*

32. *Id.*

33. *Id.*

34. *Id.* Islet cells, or islets of Langerhans, are groups of specialized cells in the pancreas that produce insulin and make and secrete hormones. *See* MedicineNet.com, *Islets of Langerhans*, *at* http://www.medicinenet.com/Script/Main/Art.asp?li=MNI&ArticleKey=4054 (last visited Jan. 28, 2001) (on file with the *University of Michigan Journal of Law Reform*).

35. *NIH Statement*, *supra* note 28.

36. *Id*; *see also* CNN.com, *Subcommittee Hears Testimony on Stem Cell Research*, *at* http://www.cnn.com/2000/Health/09/14/stemcell.hearing.02/index.html (last visited Oct. 14, 2000) (on file with the *University of Michigan Journal of Law Reform*) (recounting congres-

In a recent breakthrough, NIH scientists used the embryonic stem cells of mice to generate cells expressing insulin and other pancreatic endocrine hormones in mice with type I diabetes.[37] The cells self-assembled to form three-dimensional clusters similar to normal pancreatic islets where pancreatic cell types are closely associated with neurons.[38] Glucose triggered insulin release from these cell clusters, and when injected into mice, the insulin-producing cells maintained a clustered, islet-like organization, enabling the mice to live longer.[39] One of the researchers on this project has now moved to a private laboratory to replicate her work with HPSCs.[40]

Animal pluripotent stem cells (PSCs) also are being used by biologists at Rockefeller University in the therapeutic cloning of mice.[41] Researchers converted the skin cells of mice tails into embryonic stem cells, and colleagues at the Memorial Sloan Kettering Cancer Center then morphed those cells into the dopamine-producing cells of the brain lost in Parkinson's disease.[42] Researchers have not yet injected the dopamine-producing cells into the brains of mice with Parkinson's disease to see if the disease's symptoms are alleviated.[43]

Scientists at Johns Hopkins University are using rat PSCs to treat the animal equivalent of motor neuron disease, which paralyzes humans.[44] In laboratory experiments, rats injected with PSCs in their spinal fluid regained partial leg movement.[45] Actor and director Christopher Reeve, paralyzed from the neck down in an equestrian accident, continues to campaign for human clinical trials of this type.[46]

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sional testimony from actress Mary Tyler Moore, who has suffered from diabetes for over thirty years, discussing stem cell research in Canada where healthy pancreatic cells were transplanted into young diabetics, many of whom no longer need insulin injections).

37. Gretchen Vogel, *Stem Cells Are Coaxed to Produce Insulin*, 292 SCI. 615, 615–17 (2001).

38. *Id.* at 617.

39. *Id.*

40. Nicholas Wade, *Scientists Report 2 Major Advances in Stem-Cell Work*, N.Y. TIMES, Apr. 27, 2001, at A1.

41. Teruhiko Wakayama et al., *Differentiation of Embryonic Stem Cell Lines Generated from Adult Somatic Cells by Nuclear Transfer*, 292 SCI. 740, 740–42 (2001).

42. *Id.*

43. Wade, *supra* note 40, at A1.

44. Knight et al., *supra* note 19, at 11.

45. *Id.*

46. *Id.* at 10.

II. ETHICAL AND LEGAL ISSUES SURROUNDING RESEARCH

A. Evolving Concerns in Fetal Tissue Research

When abortion was legalized in 1973, widespread concern arose in Congress that the use of fetal tissue for transplantation might encourage pregnant women to have abortions in order to donate their fetuses for research.[47] Some women have believed that they could donate tissue to help a relative suffering from a malady such as Parkinson's disease,[48] but there is no documented instance of a woman having an abortion in order to donate fetal tissue. Several factors likely account for this. Abortion is a difficult decision for any woman to make, and it seems unlikely a woman would become pregnant intending to abort the fetus even if the purpose was to help a loved one. Also, because of the antigenetic nature of fetal tissue cells, there is a lower risk of rejection by the immune system.[49] As a result, there is much less concern with finding a compatible donor.

The concern about women aborting fetuses for research seemed to be displaced by the fear that a black market would develop in the selling of fetal tissue. The television newsmagazine *20/20* recently conducted a hidden camera investigation finding "evidence that some businessmen are trafficking in fetuses."[50] Journalist Chris Wallace interviewed Dr. Miles Jones, the owner and operator of Opening Lines, a tissue company that sells fetal parts obtained from abortion clinics to research facilities.[51] Although the law allows tissue companies to recover their costs, they are not permitted to profit from the sale of human parts,[52] but Opening Lines distributed a price list charging $325 for a spinal cord, $550 for a reproductive organ, and $999 for a brain.[53] In the following hidden

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47. Alan Fine, *The Ethics of Fetal Tissue Transplants*, HASTINGS CENTER REP., June–July 1988, at 5, 6.

48. Marlene Cimons, *Fetal Tissue Research Stirs Debate*, L.A. TIMES, Sept. 26, 1988, at B3 (discussing a wife's desire to help her ailing husband).

49. *See* Kolata, *supra* note 4, at F1.

50. *20/20: Parts for Sale* (ABC television broadcast, Mar. 8, 2000) [hereinafter *Parts for Sale*] (describing an alleged underground market for fetal parts); *see also* Kevin Murphy, *Fetal Tissue Research Complex and Divisive*, KAN. CITY STAR, Apr. 1, 2000, at A1 (discussing the FBI's investigation into whether fetal parts were illegally sold by independent companies working at a clinic in Overland Park, Kansas).

51. *Parts for Sale*, *supra* note 50.

52. 42 U.S.C. § 289(g)(2) (2000) ("It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.").

53. *Parts for Sale*, *supra* note 50 (discussing price list).

camera exchange, a *20/20* producer posing as a prospective investor met with Dr. Jones:

> PRODUCER: What does a brain go for? What does a kidney or liver go for?
>
> JONES: It's market force. It's what can you sell it for? . . . . We had projections of $50,000 a week. And you know, some weeks you can hit that and some weeks you can't. It's just a matter of being able to match supply and demand. . . . That one fetus—[for which Jones said he pays $50 and charges an average of $250] the cost of procuring it is the same whether you get one kidney or you get two kidneys, a lung, a brain, a heart. It's the same cost that you've put into it. . . . Each researcher gets charged.
>
> PRODUCER: And each time that's just money in the bank?
>
> JONES: Mm-hmm.[54]

This broadcast report led Congress to subpoena Jones to testify in its hearings on fetal tissue research in which Dean Alberty, a whistleblower from inside Jones' company, testified.[55] Alberty took $10,000 from a pro-life group to gather information, a fact included in the broadcast,[56] but he did admit to lying to the group about some of what he witnessed even though he contends his congressional testimony is true.[57] Jones was held in contempt of Congress for failing to testify,[58] and the entire matter was referred to the United States Department of Justice and the Federal Bureau of Investigation.[59]

Similar black market dangers may exist for embryos and stem cells.[60] Opponents of federal funding for stem cell research fail to realize that privately funded stem cell research lacks the scientific

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54. *Id.*

55. *Id.*

56. *Id.*

57. *Fetal Tissue Hearing: FBI Will Investigate Sales*, AM. POL. HEALTH NETWORK HEALTH LINE, Mar. 13, 2000, at 6 (summarizing Alberty's testimony).

58. H.R. REP. No. 106-527, at 4–5 (2000).

59. Letter from United States House of Representatives Committee on Commerce Democrats, to Janet Reno, Attorney General, United States Department of Justice, and Louis Freeh, Director, Federal Bureau of Investigation (Mar. 9, 2000), *at* http://www.house.gov/commerce_democrats/press/106ltr100.htm (last visited May 7, 2001) (on file with the *University of Michigan Journal of Law Reform*).

60. *See* Antonio Regalado, *Private Studies of Embryo Cells Raise Concerns*, WALL ST. J., Mar. 21, 2001, at B1 (discussing the growth of private efforts to conduct research with HPSCs).

and ethical oversight accompanying federal funding and that such an unregulated research industry may foster an underground market in stem cells.[61] A black market could be prevented, however, by awarding federally funded researchers greater autonomy. Allowing these researchers to derive their own stem cells or clone embryos[62] would reduce the incentive for black markets while allowing the researchers to have greater control over their work.

B. Special Nature of the Embryo

Ethical concerns involving stem cell research derive from what bioethicists often speak of as the moral or special nature of the embryo.[63] The embryo has qualities of a living being and a human being, but it is not a human life because it lacks neurological attributes that we ascribe to humans in the special sense.[64] An embryo is biologically alive in a general sense, but it does not have cerebral functions that give rise to consciousness.[65]

Cryopreservation, the freezing and storing of human embryos, further complicates the classification of the embryo. Scientist Lee Silver constructs a way of examining frozen embryos, the source for HPSC research, by asking whether the frozen embryo is alive.[66] The frozen embryo with all its molecules at a standstill exists in a state of suspended animation.[67] In this sense, the frozen embryo is indistinct from an inanimate object and is not alive.[68] Yet, the frozen embryo also retains the structure and genetic information of a living organism for an indefinite period, making it alive in this sense.[69] Finally, Silver asks if the frozen embryo has the potential to

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61. *Id.* (relaying the remarks of Daniel Perry, Director of the Alliance for Aging Research, a research advocacy group: "The irony is that those who have opposed federal funding claiming a moral posture seem quite unconcerned that there will be demand and supply of embryonic cells and fetal tissue, and that without government involvement it would be quite unguarded."). Only one company, the WiCell Institute, sells stem cells in the United States. *Id.* The stem cells provided by WiCell do not comply with the NIH's proposed ethical guidelines. These guidelines discourage the creation of embryos solely for research and require detailed consent from couples who choose to donate spare embryos from IVF procedures. *Id.*

62. *See infra* notes 182–84 and accompanying text.

63. *See generally* LEE SILVER, REMAKING EDEN: CLONING AND BEYOND IN A BRAVE NEW WORLD 40–47 (1997) (describing attributes of the embryo).

64. *Id.* at 41.

65. *Id.* at 22.

66. *Id.* at 79.

67. *Id.*

68. *Id.*

69. *Id.* at 79–80.

become reanimated. This question has no definitive answer since procedures for cryopreservation yield completely living embryos, completely dead embryos, and embryos combining living and dead cells.[70] Therefore, the frozen embryo is neither alive nor dead, but rather in a completely different state altogether.[71] The following examples illustrate the complications arising from the special nature of the frozen embryo.

1. Orphaned Embryos—In 1981, Mario and Elsa Rios, a California couple who had been struggling for years to conceive a child, visited an IVF clinic in Melbourne, Australia.[72] At that time, few IVF clinics existed in the United States, and, at thirty-seven, Elsa was deemed too old for treatment.[73] At the clinic, doctors discovered Mario was infertile, so the couple agreed to have three of Elsa's eggs fertilized with sperm from an anonymous donor.[74] One of the three embryos was implanted in Elsa's uterus, and the remaining two embryos were frozen.[75] Elsa miscarried soon after the implantation, and she and her husband returned home, leaving the frozen embryos in Melbourne.[76]

Several years later, Elsa and Mario were killed in a plane crash in Chile, leaving "orphaned embryos," a situation neither the Rioses nor the clinic contemplated.[77] Once it was discovered that the couple died intestate with an estate worth more than eight million dollars, women from around the world volunteered to be surrogates to bring the embryos to term in order to make a claim on the estate.[78]

In the summer of 1984, an independent commission of the government of the Australian state of Victoria, where the clinic is located, decided that the embryos should be destroyed because the Rioses did not consent to the embryos being brought to term by another woman and because the embryos had a low chance of survival given that they were frozen before the perfection of cryopreservation techniques.[79] A right-to-life outcry ensued, and

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70. *Id.* at 80.

71. *Id.*

72. *Id.* at 82 (discussing the unusual circumstances surrounding the couple's quest to conceive a child).

73. *See id.*

74. ANDREW KIMBRELL, THE HUMAN BODY SHOP: THE ENGINEERING AND MARKETING OF LIFE 91 (1993) (detailing the plight of the Rios couple).

75. *Id.*

76. *Id.*

77. SILVER, *supra* note 63, at 82.

78. *Id.* (discussing the effect of the *Daily Telegraph*'s (London) article "'Orphan' Embryo [sic] Heir to Fortune" on the willingness of women to be surrogate mothers).

79. *Id.* at 82–83.

the Victorian parliament voided the commission's recommendation and prohibited the destruction of the Rios embryos.[80] At the same time, a California court, with the agreement of the Victorian authorities, declared that neither the embryos nor the children they might become had any claim to the Rios estate.[81] A California court awarded the entire estate to the mother of Elsa Rios.[82] In 1987, the Victorian minister of health decreed that the embryos be transferred to a volunteer's womb (interest had abated because the embryos had no claim to the Rios estate), but they are still frozen in liquid nitrogen in Queen Victoria Medical Center in Melbourne where they may remain indefinitely.[83] The Rios case illustrates how ill-prepared IVF clinics were to address the complicated ethical and legal issues which could arise as a consequence of long-term embryo preservation.

2. *Ownership of Embryos*

a. Davis v. Davis—The Tennessee Supreme Court addressed the disposition of frozen embryos in *Davis v. Davis*.[84] Mary Sue Davis and Junior Lewis Davis married in 1980. Over the next four years, Mary Sue and Junior tried to achieve a normal pregnancy.[85] Mary Sue got pregnant on five separate occasions, but each time she experienced an ectopic pregnancy in which the embryo implanted in a fallopian tube instead of the uterus.[86] Mary Sue became infertile after having one of her fallopian tubes ligated to avoid further complication, and IVF became her only hope of getting pregnant.[87]

After six IVF treatments, the embryos failed to implant in Mary Sue's uterus, and the Davises decided to try cryopreservation, in which multiple embryos are generated and those not implanted are frozen in storage for later use.[88] Nine ova were retrieved, and, after fertilization, a transfer failed to result in implantation in Mary Sue's uterus; the remaining embryos stayed frozen.[89] In early 1989, Junior filed for divorce and sought joint custody of the embryos while Mary Sue sought sole custody.[90] Mary Sue wanted to keep the

80. *Id.* at 83.
81. *Id.*
82. KIMBRELL, *supra* note 74, at 92.
83. SILVER, *supra* note 63, at 83.
84. 842 S.W.2d 588 (Tenn. 1992).
85. *Id.* at 591.
86. *Id.*
87. *Id.*
88. *Id.* at 591–92.
89. *Id.* at 592.
90. *See* Davis v. Davis, No. E-14496, 1989 WL 140495, at *11 (Tenn. Cir. Ct. Sept. 21, 1989) (determining the disposition of the seven embryos).

embryos for later use, but Junior did not want any children to be produced from the embryos.[91] The trial court based its decision on the perceived desires of the embryos, treating them as children in a custody dispute.[92] The court ruled it was in the best interests of the embryos for Mary Sue to "be permitted the opportunity to bring [them] to term through implantation."[93]

The appellate court held that "it would be repugnant and offensive to constitutional principles to order Mary Sue to implant these fertilized ova against her will. It would be equally repugnant to order Junior to bear the psychological, if not the legal, consequences of paternity against his will."[94] It remanded the case to vest joint control of the embryos with Junior and Mary Sue.[95] In her appellate brief, Mary Sue indicated that she had remarried, no longer wanted the embryos to be implanted in her, and requested permission for them to be donated to an infertile couple, an issue to be addressed by the Tennessee Supreme Court.[96]

The Tennessee Supreme Court affirmed the lower court, holding that embryos "are not, strictly speaking, either 'persons' or 'property,' but occupy an interim category that entitles them to special respect because of their potential for human life."[97] The court also held that donation of the embryos to an anonymous infertile couple was impermissible as it "would rob [Junior] twice—his procreational autonomy would be defeated and his relationship with his offspring would be prohibited."[98] The court indicated that its ruling meant that the fertility clinic should follow its normal procedure for dealing with unused embryos, as long as that procedure was not in conflict with the court's ruling.[99] The court later stated in its order on a petition to rehear that the fertility clinic could not donate the surplus embryos to a childless couple, even though that was its usual procedure.[100] Instead, it mentioned the option of donating the embryos for research if both parties consented.[101] If they could not agree, the only

91. *Id.*
92. *Id.*
93. *Id.*
94. Davis v. Davis, No. 180, 1990 WL 130807, at *3 (Tenn. Ct. App. Sept. 13, 1990) (directing the lower court to award joint custody to Junior and Mary Sue).
95. *Id.*
96. *Id.* at *1 n.1.
97. Davis v. Davis, 842 S.W.2d 588, 597 (Tenn. 1992).
98. *Id.* at 604.
99. *Id.* at 605.
100. Davis v. Davis, No. 34, 1992 WL 341632, at *1 (Tenn. Nov. 23, 1992).
101. *Id.* at *2.

alternative was to discard the embryos.[102] The case was appealed to the United States Supreme Court, which denied certiorari.[103] Ultimately, Junior was awarded sole custody through further appeals, removing the requirement to obtain Mary Sue's consent on the disposition of the embryos, and the embryos were destroyed.[104]

b. Kass v. Kass—In a recent case similar to *Davis v. Davis*, the New York Court of Appeals, the state's highest court, ordered a divorced couple to abide by a signed agreement that prevented the woman from being implanted with an embryo when her ex-husband did not want a child.[105] Maureen and Steven Kass disagreed about the fate of five frozen embryos remaining in liquid hydrogen five years after their divorce.[106] Maureen wanted the embryos in order to become pregnant, but her ex-husband did not want to raise a child with her.[107] The court relied on an informed consent agreement signed by the couple before the cryopreservation procedure.[108] In the informed consent document, the Kasses agreed that if they no longer wished to initiate a pregnancy, they would donate the frozen embryos for biological studies and research approved by the clinic's IVF program.[109]

In *Davis*, the court stated that if the Davises consented, it would defer to a disposition suggested by the American Fertility Society's Ethics Committee calling for donation of the embryos for medical research.[110] In *Kass*, the court invoked contract law, in which the former couple signed an informed consent document choosing to donate their embryos for research in the event that they could not make a united decision on the disposition of the embryos.[111] Both courts acknowledged the special nature of the embryo in its usefulness for medical research as a preferred alternative to destruction. Both courts recognized a dignity inherent in the embryo that prefers the use of the embryos for implantation, or, if not, at least for a noble purpose such as medical research. As a result of the widely publicized situation involving the orphaned

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102. *Id.*

103. Davis v. Davis, No. 34, 1992 WL 341632 (Tenn. Nov. 23, 1992), *cert. denied* 507 U.S. 911 (1993).

104. *Embryos from Court Battle are Destroyed*, COM. APPEAL (Memphis, Tenn.), June 15, 1993, at B3.

105. Kass v. Kass, 696 N.E.2d 174, 181 (N.Y. 1998).

106. *Id.* at 175.

107. *Id.*

108. *Id.* at 182.

109. *Id.* at 176–77.

110. Davis v. Davis, No. 34, 1992 WL 341632, at * 2 (Tenn. Nov. 23, 1992).

111. *Kass*, 696 N.E.2d at 176–77.

embryos in Australia and the proliferation of cryopreservation techniques, IVF clinics created informed consent forms addressing the disposition of frozen embryos in the event of separation, divorce, death, or lack of interest in becoming pregnant.[112] The option allowing for donation for medical research purposes shows the value placed on the continued use of the embryo for a life-giving purpose even if the embryo itself will not develop into a human being.

3. Abandoned Embryos—In Great Britain, the government became involved in the disposition of frozen embryos when it passed a law in 1990 allowing for the destruction of all unclaimed frozen embryos within five years of the law's effective date, August 1, 1991.[113] The law gained worldwide attention in the months before August 1, 1996, when more than 9000 frozen embryos, which had been in storage prior to the law's effective date, were subject to destruction.[114] In the months before the deadline, IVF clinics attempted to contact all of the couples who had not indicated what they wanted to do with their stored embryos.[115] The couples responding accounted for 6000 of 9000 embryos; of those responding, forty-seven percent offered them for research, thirty percent decided to keep them in storage for future use, fifteen percent donated them to other couples, and only eight percent agreed to allow the embryos to be destroyed.[116] The clinics did attempt to locate all of the couples who had frozen embryos in storage. Unclaimed embryos were deemed abandoned. Consequently, these embryos were to be thawed out, with a drop of water or alcohol then added, causing the cells to disintegrate.[117] Many pro-life groups protested the government's decision, including a Roman Catholic group of more than 100 Italian women, including two elderly nuns, who offered to adopt the embryos.[118] What the

112. *See* Lauri Gray Eaton, *Extra Embryos: What Is Their Future?*, NORTHSIDE RECORDER (San Antonio, Tex.), Jan. 4, 2001, at 28 (explaining that most IVF clinics require couples to sign informed consent forms with options of donating the embryos for scientific research, donating the embryos to an infertile couple, or discarding the embryos).

113. Fred Barbash, *British Frozen Embryos Face Disposal; Thousands of Fertilized Eggs Reach Legal Deadline for Thawing*, WASH. POST, Aug. 1, 1996, at A1 (describing opposition to the British government's plan to dispose of unclaimed frozen embryos).

114. *Id.*

115. *Id.*

116. Jeremy Laurance, *Plea to Couples to Save 3,300 Embryos from Destruction*, TIMES (London), July 23, 1996, at Home News Section, *available at* 1996 WL 6508344 (discussing the efforts by IVF clinics to locate prospective parents of frozen embryos).

117. *Id.*

118. Philip Willan, *Italians in Bid to Save Embryos*, TIMES (London), July 27, 1996, at Overseas News Section, *available at* 1996 WL 6509260.

group hoped to do with the embryos is unclear; its primary goal appeared to be preventing the destruction of the embryos.

There are no federal laws in the United States permitting the destruction of frozen embryos without the consent of the donors. Although nearly half of the British couples initially contacted showed a preference for donating their embryos for research, the British government chose to destroy the embryos without consent rather than donate the embryos for research without consent. If diligent efforts were made to locate the donors accounting for the 3000 unclaimed embryos, the presumption should be that those embryos were abandoned and could be put to use for research. The British law, however, requires donor consent to preserve an embryo longer than five years;[119] it mandates destruction after a period corresponding to the age of the female donor.[120] Perhaps this indicates the British government's disregard for the notion of the special nature of the embryo, a recognition which allows for destruction without consent, but also makes research less likely to be inhibited by Parliament if it does not believe that the embryo is something special. Such an attitude makes British research involving embryos far less restricted than such research in the United States, even to the point where embryos soon will be cloned for research purposes in Great Britain.[121]

Law and society will continue to wrestle with how to address the special nature of the embryo. There are those who believe that the embryo should be treated with all the same rights as a person because the unique genetic makeup of the embryo is complete at conception.[122] Adherents of this view object to the intentional destruction of embryos as well as research that will result in destruction.[123] They also object to IVF in general because it results in surplus embryos, and therefore the most acceptable solution to them is to donate the extra embryos to infertile couples.[124] This viewpoint is strongly linked to anti-abortion sentiment, likening the harvesting of stem cells to abortion because the act of deriving

119. Human Fertilisation and Embryology Act, c. 37, § 14 (1990) (Eng.).

120. Human Fertilisation and Embryology Regulations, §§ 2(1), 3 (1996) (Eng.).

121. Sarah Hall & Tim Radford, *Peers Vote to Permit New Research on Embryos*, GUARDIAN (London), Jan. 23, 2001, at 2 (describing the newly enacted British law allowing scientists to clone embryos and keep them alive for up to fourteen days to extract stem cells).

122. *See* Carl H. Coleman, *Procreative Liberty and Contemporaneous Choice: An Inalienable Rights Approach to Frozen Embryo Disputes*, 84 MINN. L. REV. 55, 66 (1999) (discussing the varying views of the moral status of human embryos).

123. *Id.* at 66–67.

124. *Id.* at 67.

the HPSCs destroys the live embryo.[125] Proponents of this view staunchly equate federal funding of stem cell research with complicity in the taking of human life.[126] On the other side, there are those who believe that embryos do not have a special moral status and should be viewed merely as property.[127] This view allows for the destruction of embryos for any reason, including research.[128]

Adherents of the middle position, that the embryo is something other than living or dead, do not object to the destruction of unwanted embryos or to their use for scientific and medical research.[129] Indeed, the American Medical Association has stated that frozen embryos may be donated, but not sold, to infertile couples or researchers, or may be allowed to thaw and deteriorate.[130] Acknowledging that the embryo is alive, but that its special nature comes from the recombinant DNA within it, may be one step toward appeasing stem cell research opponents.[131] This argument rests on the fact that DNA is the personifying feature of a 100-cell blastocyst, rather than the egg wall, cytoplasm, and mitochondria, which are destroyed in stem cell derivation.[132] HPSCs derived from harvested embryos are directed to form cell lines, each of which contains, in dormant form, the full component of embryonic DNA.[133] The DNA has a higher probability of existing for many years than the DNA of a frozen embryo, which will most

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125. *See* Richard M. Doerflinger, *The Ethics of Funding Embryonic Stem Cell Research: A Catholic Viewpoint*, 9 KENNEDY INST. ETHICS J. 137, 141 (1999).

126. *See id.* at 145–46.

127. Coleman, *supra* note 122, at 67.

128. *See* R. Alta Charo, *The Hunting of the Snark: The Moral Status of Embryos, Right-to-Lifers, and Third World Women*, 6 STAN. L. & POL'Y REV. 11, 16 (1995) (asking if the potential to be born entitles an entity to be treated as if it already were born (citing Michael Tooley, *In Defense of Abortion and Infanticide*, *in* WHAT IS A PERSON? 83–114 (Michael F. Goodman ed., 1988) (characterizing the problem of labeling the destruction of potential as wrong when the being with the potential to be born has no ability to perceive it is being wronged))).

129. Coleman, *supra* note 122, at 69 n.66 (explaining that most supporters of this view favor limiting embryo research to the first fourteen days of development before the "primitive streak," the precursor of the nervous system, develops) (citing John A. Robertson, *Embryos, Families, and Procreative Liberty: The Legal Structure of the New Reproduction*, 59 S. CAL. L. REV. 939, 983–84 (1986)).

130. *See* Heidi Forster, *Recent Development, The Legal and Ethical Debate Surrounding the Storage and Destruction of Frozen Human Embryos: A Reaction to the Mass Disposal in Britain and the Lack of Law in the United States*, 76 WASH. U. L.Q. 759, 766 (1998) (citing COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, AMERICAN MED. ASS'N, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS § E-2.141 (1994)).

131. Glenn McGee & Arthur Caplan, *The Ethics and Politics of Small Sacrifices in Stem Cell Research*, 9 KENNEDY INST. ETHICS J. 151, 154 (1999).

132. *Id.* at 155.

133. *Id.*

likely be discarded by an IVF clinic.[134] In this sense, the life within the embryonic DNA lives on in the HPSCs derived from the embryo.

III. CURRENT STATE OF FEDERAL LAW

A. Federal Law on Fetal Tissue Research

The United States Supreme Court decision in *Roe v. Wade*[135] in 1973 forever politicized the abortion debate.[136] The Court held in *Roe* that, absent a compelling state interest in protecting her health, a woman has the right to choose whether to terminate her pregnancy based on a fundamental privacy right.[137] Justice Blackmun adopted a trimester analysis, where the state has no interest in the first trimester but has a compelling interest in the woman's health in the second trimester because abortion becomes much more dangerous after the first twelve weeks of pregnancy.[138] The state acquires an interest in protecting the life of the fetus either when it reaches the third trimester or when it reaches the point of viability.[139]

In the wake of *Roe*, Congress grew concerned about the possibility of the exploitation of fetuses from elective first- and second-trimester abortions and enacted a moratorium on federal funding of fetal tissue research in 1974.[140] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was given a congressional mandate to recommend a

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134. *Id.*

135. 410 U.S. 113 (1973).

136. *See generally* BARBARA H. CRAIG & DAVID M. O'BRIEN, ABORTION & AMERICAN POLITICS (1993) (discussing how the abortion controversy has played out in the operation of American government and politics); CYNTHIA GORNEY, ARTICLES OF FAITH: A FRONTLINE HISTORY OF THE ABORTION WARS (1998) (presenting a political and social narrative of the significant years in the abortion conflict through interviews with people on both sides of the issue); JAMES RISEN & JUDY THOMAS, WRATH OF ANGELS: THE AMERICAN ABORTION WAR (1998) (tracing the evolution of the anti-abortion movement and its role in the creation of the religious right); LAURENCE H. TRIBE, ABORTION: THE CLASH OF ABSOLUTES (1990) (attempting to explain and justify the constitutional theory of reproductive freedom).

137. *Roe*, 410 U.S. at 163–65.

138. *Id.* at 155–65.

139. *Id.* at 165. In 1992, the United States Supreme Court affirmed, but weakened, the right to an abortion. *See* Planned Parenthood of S.E. Penn. v. Casey, 505 U.S. 833, 846–51, 869 (1992) (upholding restrictive Pennsylvania abortion legislation, except for spousal-notice provisions, under the due process clause of the Fourteenth Amendment).

140. *See* National Research Service Award Act, 42 U.S.C. § 289(e)-1 (1974).

framework for federal regulations governing fetal tissue research.[141] The regulations arising from those recommendations provided for the establishment of ethical advisory boards (EABs) able to handle all the complex issues related to fetal tissue research including legal, ethical, and medical issues.[142] The EABs were supposed to advise the Secretary of Health and Human Services (HHS) regarding issues raised by individual research proposals.[143] The first EAB did not convene until 1978, however, at which time research on fetal tissue from nonviable fetuses obtained from elective abortions commenced under strict guidelines. This research continued until March 1988 when the NIH banned all fetal tissue research involving tissue obtained from electively aborted fetuses.[144] This measure ostensibly was taken out of fear that the laudable goals of fetal tissue research might destigmatize the abortion procedure and make it more acceptable in society.

Acknowledging the importance of fetal tissue research, President George H.W. Bush issued an executive order in 1992 calling for the establishment of a national fetal tissue bank without lifting the moratorium on federal funding of fetal tissue research involving electively aborted fetuses.[145] The fetal tissue in the bank was to be obtained "exclusively from ectopic pregnancies and spontaneous abortions."[146] Tissue from the bank was to be made available to "physicians and hospitals interested in using the tissue from the bank to further specific medical objectives."[147] The fetal tissue bank still did not permit fetal tissue obtained from elective abortions to be included in the bank, even though tissue from aborted fetuses is most useful in fetal tissue research because it is typically not pathologically flawed as is tissue from ectopic pregnancies and spontaneous abortions.[148]

Finally, in 1993, President Bill Clinton ordered the repeal of the moratorium on fetal tissue research involving electively aborted fetuses because it has "significantly hampered the development of possible treatments for individuals afflicted with serious diseases

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141. *See* National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: Research on the Fetus, Report and Recommendations, 40 Fed. Reg. 33,350 (1975) (codified at 45 C.F.R. §§ 46.101–301).

142. 45 C.F.R. § 46.204(a) (1987).

143. 45 C.F.R. § 46.204(b) (1987).

144. Kolata, *supra* note 4, at F1 (discussing the HHS assistant secretary's ban of federal funding of fetal tissue research).

145. Exec. Order No. 12,806, 57 Fed. Reg. 21,589 (May 19, 1992) (establishing a national fetal tissue bank).

146. *Id.*

147. *Id.*

148. Fackelmann, *supra* note 11, at 6.

and disorders, such as Parkinson's disease, Alzheimer's disease, diabetes, and leukemia."[149] The law currently allows for the use of human fetal tissue from elective abortions if the donor gives consent and if there is no alteration of the abortion procedure in order to facilitate obtaining the tissue.[150] Congress passed another law making it "unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."[151] This law was designed to address possible trafficking in fetal tissue and may become more strictly enforced. In the last six years, the NIH has awarded approximately $110 million in grants for fetal tissue research, largely for the study of diabetes, digestive, kidney, and nerve diseases.[152] Federally funded fetal tissue researchers are still struggling to make up for the nearly five years they lost when federally funded fetal tissue research involving electively aborted fetuses was banned.

B. Federal Law on Stem Cell Research

In 1980, Congress passed a law allowing federal funding of embryological research following a favorable review by the HHS EAB regarding ethical issues for a specific project.[153] The EAB concluded IVF research was acceptable, but because the NIH did not initiate any projects involving embryological research, no research was funded.[154] In 1993, Congress repealed the regulation so that embryological research could receive federal funding unless an EAB made a contrary finding.[155]

The NIH formed the Human Embryo Research Panel to promulgate guidelines for reviewing grant requests, and the panel recommended proceeding with embryological research on September 27, 1994.[156] The NIH Advisory Committee to the Director

149. Memorandum for the Secretary of Health and Human Services, Federal Funding of Fetal Tissue Transplantation Research, 58 Fed. Reg. 7,457, 7,457 (Jan. 22, 1993).

150. 42 U.S.C. § 289g-1(b)(2) (1994).

151. 42 U.S.C. § 289g-2(a).

152. Murphy, *supra* note 50, at A1 (outlining the positions of proponents and opponents of fetal tissue research).

153. *See* Health and Human Services Policy for Protection of Human Subjects Research, 59 Fed. Reg. 28,276, 28,276 (June 1, 1994) (to be codified at 45 C.F.R. pt. 46).

154. *Id.*

155. *See id.*

156. Laurie McGinley, *U.S. Panel Backs Human-Embryo Studies*, ASIAN WALL ST. J., Sept. 29, 1994, at 26.

voted to accept the panel's report, but on December 2, 1994, President Clinton directed the NIH to forgo funding any projects involving the creation of embryos solely for research.[157] Embryological research was further hampered by the budget compromise in 1996 that prohibited the use of federal funds for the creation of human research embryos or embryo research in which the embryo is destroyed, such as the derivation of HPSCs.[158]

On January 15, 1999, HHS issued a legal opinion finding that the statutory prohibition of the use of federal funds for human embryological research would not apply to research using HPSCs because HPSCs do not constitute an embryo.[159] According to Dr. Harold Varmus, the former NIH Director, research on HPSCs is different from research on embryos because HPSCs do not have the capacity to become human beings.[160] On August 25, 2000, the NIH authorized federal funding for research involving HPSCs in a narrow sense.[161] Studies using HPSCs derived from human embryos may be conducted with NIH funds only if the HPSCs were derived without federal funds "from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment."[162] Although NIH researchers are not allowed to derive HPSCs, federal funds may be used to support research deriving cells from fetal tissue, a curious anomaly.[163]

In April 2001, Sen. Arlen Specter (R-Pa.) introduced the Stem Cell Research Act of 2001 in order to provide more freedom for federally funded researchers to work with HPSCs. Sen. Specter explained the purpose of the Stem Cell Research Act of 2001:

> [W]e have a duty to accelerate medical research by allowing researchers to utilize Federal funds to derive their own stem cells. Human embryonic stem cell research holds such potential for millions of Americans who are sick and in pain that we believe it is wrong for us to prevent or delay our world-class scientists from building on the progress that has been made. Our legislation creates one narrow and specific source for

157. John Schwartz & Ann Devroy, *Clinton to Ban U.S. Funds for Some Embryo Studies*, WASH. POST, Dec. 3, 1994, at A1.

158. *See* Balanced Budget Downpayment Act of 1996, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34.

159. 146 CONG. REC. S150, 150 (daily ed. Jan. 31, 2000) (statement of Sen. Specter) [hereinafter SPECTER STATEMENT].

160. *Id.*

161. *See Guidelines on Pluripotent Stem Cells*, *supra* note 24.

162. *Id.*

163. *Id.*

> Federal researchers to obtain embryos for use in stem cell research: embryos which would otherwise be discarded from in-vitro fertilization clinics, with the expressed consent of the donating families. In addition, a provision is included which requires that all Federally-funded research must adhere to strict procedural and ethical guidelines to ensure that such research is conducted in an ethical, sound manner. It is important to note that as it stands today, embryonic stem cell research in the private sector is not subject to Federal monitoring or ethical requirements. [164]

The bill would grant permanent authority to the HHS Secretary to fund research on human embryos solely for the purpose of generating stem cells.[165] Only embryos discarded and donated by IVF clinics with the informed consent of the donors would be permitted.[166] Sen. Specter acknowledged in a news conference that the bill is going to be controversial and noted that the "jury is still out on how it will come out."[167] The bill has been referred to the Senate Health, Education, Labor, and Pensions Committee for review.[168]

CONCLUSION

In the course of the debate involving abortion (fetal tissue research), and the "killing" of potential human life (stem cell research), an implicit hierarchy developed affording the fetus the most legal protection, followed by the human embryo, and then the HPSC. Somewhere in this chain lie fetal parts, ostensibly granted less protection because they do not constitute a whole being, and because they do not have the potential to become alive. Lately, though, the paradigm has shifted. There are actually fewer restrictions on fetal tissue research than on research involving HPSCs. Why should there be more protection for discarded human embryos and the stem cells within them? Discarded embryos result from a decision by the donors not to implant the embryos for pregnancy. Recognizing their potential to become human beings belies the fact that these discarded embryos were abandoned

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164. 147 CONG. REC. S3553, 3553 (daily ed. Apr. 5, 2001) (statement of Sen. Specter).

165. S. 723, 107th Cong. § 1 (2001).

166. *Id.*

167. *Stem Cell Bill Hits Senate Floor*, BLUE SHEET, Apr. 11, 2001, *available at* 2001 WL 7811152.

168. S. 723, 107th Cong. § 1 (2001), *available at* http://thomas.loc.gov.

by their donors. A true supporter of the sanctity of human life should see the invaluable contributions that HPSCs can make in improving the lives of those already living.

Some scientists fear that the new pro-life Republican administration may stop federally funded HPSC research.[169] Indeed, President George W. Bush has stated his opposition to embryonic stem cell research, and HHS Secretary Tommy Thompson successfully evaded the issue in his Senate confirmation hearings.[170] Those who support the pro-life position should want to see HPSCs put to use to improve the lives of those living in agony. Yet, the vehement opposition once leveled against the use of fetal tissue now seems directed against stem cell research.[171]

Those opposed to stem cell research may be persuaded to change their minds if further studies demonstrate the promise of stem cells in treating virulent diseases. The best way to do that is to allow federally funded research to proceed. Even staunch pro-life Sen. Gordon Smith (R-Or.), whose family has been affected by

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169. *See* Sandra Blakeslee, *In Early Experiments, Cells Repair Damaged Brains*, N.Y. TIMES, Nov. 7, 2000, at F1 (discussing the promise of stem cell research); *see also* Michael J. Fox, Editorial, *A Crucial Election for Medical Research*, N.Y. TIMES, Nov. 1, 2000, at A33 (referring to comments made by campaign aides to then Governor George W. Bush that his administration would ban federal funding for stem cell research). Numerous groups have lobbied President Bush to support stem cell research, including eighty Nobel laureates who urged him not to block federal funding for the research. Rick Weiss, *Nobel Laureates Back Stem Cell Research*, WASH. POST, Feb. 22, 2001, at A2.

170. Sheryl Gay Stolberg, *Stem Cell Research Advocates in Limbo*, N.Y. TIMES, Jan. 20, 2001, at A17 (showing President Bush's opposition to federal funding of "experimentation on embryonic stem cells that require live human embryos to be discarded or destroyed"). Although HHS Secretary Thompson supported privately funded stem cell research while governor of Wisconsin, his position on federal funding remains unknown. *See id.* President Bush directed Thompson to review the HHS stem cell research policy, and Thompson has promised to make a recommendation by summer on whether federally funded stem cell research will proceed. Marlene Cimons, *Stem Cell Study Decision Due by Summer*, L.A. TIMES, Mar. 1, 2001, at A16. In April, HHS canceled the inaugural meeting of the NIH committee that was to review the first applications from scientists seeking federal funds for HPSC research. Rick Weiss, *Bush Administration Order Halts Stem Cell Meeting*, WASH. POST, Apr. 21, 2001, at A2. The meeting of the newly formed Human Pluripotent Stem Cell Review Group, which includes scientific, ethical, and theological experts, has not been rescheduled. *Id.* The NIH, which was recently offered a 13.5% increase in its budget for the upcoming fiscal year by the Bush administration, did not fight the cancellation of the committee meeting. *Id.*

171. 145 CONG. REC. E1696, 1697 (July 30, 1999) (quoting Rep. Bob Schaffer (R-Colo.)) ("The logic of this practice is not unlike that of the Third Reich, where torture was rationalized for medical research. It is something no civilized nation should condone, much less fund with tax dollars of conscientious, disapproving Americans."); *see, e.g.*, Bill Tammeus, Editorial, *When Science Outruns Common Knowledge*, KAN. CITY STAR, Sept. 3, 2000, at B11 (referring to Sen. Sam Brownback (R-Kan.), who described stem cell research as "illegal, immoral and unnecessary").

Parkinson's disease, supports this expansion of embryonic stem cell research.[172]

Another effective means of gathering support for stem cell research involves further using celebrities to raise awareness.[173] Christopher Reeve, the quadriplegic actor and director, actively campaigns for using HPSCs to repair spinal cord damage.[174] Actor Michael J. Fox has testified before the United States Senate on behalf of Parkinson's disease research.[175] This type of attention could motivate the public to become more involved and lobby Congress for government funding for research.[176]

Ronald Green, Director of the Dartmouth College Ethics Institute,[177] has suggested policy determinations involving HPSCs proceed on the theory of "public reason."[178] "Public reason" entails using arguments that appeal to widely shared human values and avoid appeal to religious or moral claims that are unsustainable on common sense or evidentiary grounds.[179] Such public values include access to publicly funded health-related research.[180] Green acknowledges the right to discuss objections to such research, but

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172. Robin Toner, *The Abortion Debate, Stuck in Time*, N.Y. TIMES, Jan. 21, 2001, § 4, at 1 (quoting Sen. Smith as saying " 'My pro-life beliefs guide me to make life better for the living as well, to relieve suffering where there is pain, and to find cures for deadly diseases wherever possible.' "). Other pro-life supporters of HPSC research include Sen. Strom Thurmond (R-S.C.) and former Sen. Connie Mack (R-Fla.). Aaron Zitner & Marlene Cimons, *Nominee Crosses Stem Cell Divide*, L.A. TIMES, Jan. 18, 2001, at A13.

173. Mark Ebner & Lisa Derrick, *Star Sickness: Celebrities Speaking Out About Their Afflictions Can Raise Awareness and Money*, SALON.COM, Nov. 29, 1999, *at* http://www.salon.com/health/feature/1999/11/29/celeb_disease/index.html (on file with the *University of Michigan Journal of Law Reform*) (discussing how celebrities, through congressional testimony and public awareness campaigns, have put familiar faces on diseases that otherwise might have hovered below the high-profile funding radar).

174. *Good Morning America: Christopher and Dana Reeve Discuss Fundraising and Research on Behalf of Spinal Cord Injuries* (ABC television broadcast, Mar. 19, 2001) (announcing the formation of a coalition of medical researchers and drug companies to advance stem cell research).

175. Ebner & Derrick, *supra* note 173 (quoting Michael J. Fox as saying, " 'What celebrity has given me is the opportunity to raise the visibility of Parkinson's disease and focus attention on the desperate need for more research dollars.' ").

176. *See id.*

177. The Dartmouth College Ethics Institute recently sponsored a symposium on the scientific and ethical issues surrounding stem cell research. *See Realvideo Presentations of . . . A Student Science Court: The Future of Stem Cell Research*, *at* http://www.dartmouth.edu/~ethics/start.htm (Jan. 29, 2000) (on file with the *University of Michigan Journal of Law Reform*).

178. Ronald M. Green, *Stopping Embryo Research*, 9 HEALTH MATRIX: J. L.-MED. 235, 248 (1999) (citing John Rawls, *The Idea of Public Reason*, *in* POLITICAL LIBERALISM 212 (1993) (delineating how a political society forms its plans, prioritizes its results, and makes decisions)).

179. *See id.*

180. *See id.*

argues that religious and ethical claims that cannot withstand objectively reasoned analysis should not play a role in these discussions.[181]

Unfortunately, this issue is complicated by the special nature of the embryo. The frozen embryo, in particular, exists on a plane distinct from something that is clearly alive or clearly dead. It may seem difficult to reconcile consciously destroying something that was deliberately created. Perhaps that is why the United States should follow the lead of Great Britain, which became the first nation to legalize the cloning of human embryos for research.[182] Congress has forbidden federal funding for the cloning of human embryos specifically for research purposes,[183] but these would be embryos created not for reproduction but specifically to derive HPSCs. Creating embryos knowing that they are going to be used to derive HPSCs may reduce the intensity of the special nature of the embryo. HPSCs do not have the capacity to become human beings, so fears of a *Brave New World* scenario are unfounded.[184]

Although the ideal situation pictures NIH researchers cloning embryos and then deriving stem cells, realistically, small steps must be taken to achieve great strides. The first and most important step involves passing the Stem Cell Research Act of 2001 to allow federally funded researchers the ability to conduct scientific research absent arbitrary restrictions.[185] The Act would permit

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181. *See id.* at 248–51 (citing Alex Mauron, *The Human Embryo and the Relativity of Biological Individuality*, *in* CONCEIVING THE EMBRYO: ETHICS, LAW AND PRACTICE IN HUMAN EMBRYOLOGY 55, 66–67 (Donald Evans, ed., 1986)). Using Swiss philosopher Alex Mauron's discussion of the ethical challenges surrounding those holding idiosyncratic moral beliefs, Green argues it would violate public ethics in a pluralistic democracy for such people to impose their non-publicly sustainable views on others and would corrupt the integrity of an independently established scientific review process.

182. The House of Commons approved the measure by a vote of 366 to 174, amending the Human Fertilisation and Embryology Act to allow human embryo cloning for stem cell research. *British Bill on Human Embryo Clones Gains*, N.Y. TIMES, Dec. 20, 2000, at A20. The House of Lords later approved the measure 212 to 92. Hall & Radford, *supra* note 121, at 2.

183. Consolidated Appropriations Act, 2001, Pub. L. No. 106-554, 114 Stat. 2763, 2763A-71 (2000). Federal funding for this activity has been forbidden for more than five years. Consolidated Appropriations Act, 2000, Pub. L. No. 106-113, 113 Stat. 1501, 1501A-275 (1999); Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277, 112 Stat. 2681, 2681–386 (1998); Departments of Labor, Health and Human Services, and Related Agencies Appropriations Act, 1998, Pub. L. No. 105-78, 111 Stat. 1467, 1517 (1997); Omnibus Consolidated Appropriations Act, 1997, Pub. L. No. 104-208, 110 Stat. 3009, 3009–270 (1996).

184. *See generally* ALDOUS HUXLEY, BRAVE NEW WORLD (Perennial Classics 1998) (1932) (envisioning a world in which the population is divided into five castes, governed by supply and demand, and the number of people is controlled by adjusting test tube births and multiplying embryos that will be born into the lower castes).

185. In January 2000, Sen. Specter and Sen. Tom Harkin (D-Iowa) introduced the Stem Cell Research Act of 2000, identical to the Stem Cell Research Act of 2001, but the bill never

these researchers to actually work with embryos discarded from IVF clinics and to derive the HPSCs on their own without relying on private researchers to do it for them.

Allowing federally funded researchers this level of autonomy will greatly accelerate advances in the study of diseases and expedite the development of necessary treatments. Enough time has been wasted leveraging for political gain in the debates surrounding fetal tissue research and stem cell research. It is time for the political semantics to end and for life-saving research to begin unencumbered.

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left the Senate Health, Education, Labor, and Pensions Committee for a debate on the Senate floor. S. 2015, 106th Cong. § 2 (2000), *available at* http://thomas.loc.gov. Senate Majority Leader Trent Lott (R-Miss.) indicated his willingness to "make sure it will not fall through[,]" but there was no further activity on the Act. 146 CONG. REC. S9448 (Sept. 28, 2000) (statement of Sen. Lott). Rep. Carolyn Maloney (D-N.Y.) and Rep. Connie Morella (R-Md.) recently introduced a resolution in the 107th Congress, supporting federal funding of pluripotent stem cell research, but the resolution does not call for allowing federally funded researchers to derive their own stem cells. H.R. Con. Res. 17, 107th Cong. (2001), *available at* http://thomas.loc.gov.